



Clinical trial results:

Ancillary study evaluating ChAd155-hli-HBV shedding in a subset of chronic hepatitis B patients enrolled in the first-time-in-human, Phase I/II, randomised, multi-centric, single-blind study TH HBV VV-001

Summary

EudraCT number	2017-002574-39
Trial protocol	DE
Global end of trial date	02 March 2022

Results information

Result version number	v1 (current)
This version publication date	23 October 2025
First version publication date	23 October 2025

Trial information

Trial identification

Sponsor protocol code	207811
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	GlaxoSmithKline
Sponsor organisation address	79 New Oxford Street, London, WC1A 1DG, United Kingdom, TW8 9GS
Public contact	GSK Response Center, GlaxoSmithKline, 44 8664357343, GSKClinicalSupportHD@gsk.com
Scientific contact	GSK Response Center, GlaxoSmithKline, 44 8664357343, GSKClinicalSupportHD@gsk.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	18 July 2022
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	02 March 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the shedding of ChAd155-hIi-HBV following intramuscular administration.

Protection of trial subjects:

The specific measures that were put in place to protect the participants in the TH HBV VV-001 (2017-001452-55) primary study are also applicable for the sub-population included in this ancillary study. Internal Safety Review Committee (iSRC) oversaw the safety and wellbeing of the study participants, with a set of pre-defined holding rules in place.

An external (non-GSK) expert with clinical expertise in hepatology worked together with the iSRC to review the safety data and contribute to the decision-making process to hold or continue the study. In the TH HBV VV-001 primary study, vaccines were administered only to eligible participants that had no contraindications to any components of the vaccine. Vaccines were administered by qualified and trained personnel.

All participants were observed closely for at least 60 minutes following the administration of the vaccines in the TH HBV VV-001 primary study, with appropriate medical treatment readily available in case of an immediate systemic allergic reaction. All participants were closely followed up for adverse events for 2.5 years.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	27 October 2020
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	France: 1
Country: Number of subjects enrolled	Germany: 9
Country: Number of subjects enrolled	Spain: 18
Country: Number of subjects enrolled	Taiwan: 11
Country: Number of subjects enrolled	Thailand: 12
Country: Number of subjects enrolled	United Kingdom: 2
Worldwide total number of subjects	53
EEA total number of subjects	28

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	52
From 65 to 84 years	1
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was conducted at 21 centers in 6 countries: 5 in Germany, 1 in UK, 5 in Taiwan, 1 in France, 2 in Thailand and 7 in Spain.

Pre-assignment

Screening details:

Out of the 53 participants enrolled in the current ancillary study, 1 participant was eliminated due to protocol deviations, and hence, 52 participants were included in the Exposed set and completed the study.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Single blind
Roles blinded	Subject

Blinding implementation details:

Blinding in this study was directly linked to the blinding in the TH HBV VV-001 (2017-001452-55) primary study. For laboratory testing, samples were not labelled with any reference to the participant number used in the TH HBV VV-001 primary study in order to keep that study blinded.

Arms

Are arms mutually exclusive?	Yes
Arm title	B1 Group

Arm description:

Participants received one dose of ChAd155-hIi-HBV high dose formulation vaccine at Day 1 in step B of the TH-HBV VV-001 (2017-001452-55) primary study and were evaluated for ChAd155-hIi-HBV shedding in the current ancillary study.

Arm type	ChAd155-hIi-HBV shedding evaluation
Investigational medicinal product name	ChAd155-hIi-HBV high dose formulation
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

No study intervention was administered in this ancillary study. Participants received one dose of ChAd155-hIi-HBV high dose formulation vaccine at Day 1 in step B of the TH-HBV VV-001 (2017-001452-55) primary study.

Throat swab and urine samples were collected from all participants at Day 1 (before study intervention administration in the TH HBV VV-001 primary study), Day 3, Day 8, Day 15 and Day 31 in the current ancillary study.

Arm title	Control Group
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Arm description:

Participants received either one dose of HBc-HBs/AS01B-4 high dose formulation vaccine at Day 1 or one dose of negative control (placebo) at Day 1 in step B of the TH-HBV VV-001 (2017-001452-55) primary study and were evaluated for ChAd155-hIi-HBV shedding in the current ancillary study.

Arm type	ChAd155-hIi-HBV shedding evaluation
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intramuscular use

Dosage and administration details:

No study intervention was administered in this ancillary study. Participants received one dose of Placebo at Day 1 in step B of the TH-HBV VV-001 (2017-001452-55) primary study.

Throat swab and urine samples were collected from all participants at Day 1 (before study intervention administration in the TH HBV VV-001 primary study), Day 3, Day 8, Day 15 and Day 31 in the current ancillary study.

Investigational medicinal product name	HBC-HBs/AS01B-4 high dose formulation
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and suspension for suspension for injection
Routes of administration	Intramuscular use

Dosage and administration details:

No study intervention was administered in this ancillary study. Participants received one dose of HBC-HBs/AS01B-4 high dose formulation vaccine at Day 1 in step B of the TH-HBV VV-001 (2017-001452-55) primary study.

Throat swab and urine samples were collected from all participants at Day 1 (before study intervention administration in the TH HBV VV-001 primary study), Day 3, Day 8, Day 15 and Day 31 in the current ancillary study.

Number of subjects in period 1^[1]	B1 Group	Control Group
Started	24	28
Completed	24	28

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: Out of the 53 participants enrolled in the current ancillary study, 1 participant was eliminated due to protocol deviations, and hence, 52 participants were included in the Exposed set and completed the study.

Baseline characteristics

Reporting groups

Reporting group title	B1 Group
Reporting group description:	
Participants received one dose of ChAd155-hIi-HBV high dose formulation vaccine at Day 1 in step B of the TH-HBV VV-001 (2017-001452-55) primary study and were evaluated for ChAd155-hIi-HBV shedding in the current ancillary study.	
Reporting group title	Control Group
Reporting group description:	
Participants received either one dose of HBc-HBs/AS01B-4 high dose formulation vaccine at Day 1 or one dose of negative control (placebo) at Day 1 in step B of the TH-HBV VV-001 (2017-001452-55) primary study and were evaluated for ChAd155-hIi-HBV shedding in the current ancillary study.	

Reporting group values	B1 Group	Control Group	Total
Number of subjects	24	28	52
Age Categorical			
Units: Participants			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			
Age Continuous			
Age at first vaccination in the TH-HBV VV-001 (2017-001452-55) primary study.			
Units: years			
arithmetic mean	48.5	49.7	
standard deviation	± 8.6	± 7.1	-
Gender Categorical			
Units: Participants			
Female	5	7	12
Male	19	21	40
Race/Ethnicity, Customized			
The "All Other Races" category (i.e., Black Or African American and White where 0<n<11) are combined into one category to maintain participant confidentiality and privacy.			
Units: Subjects			
Asian	12	12	24
All Other Races	12	16	28

End points

End points reporting groups

Reporting group title	B1 Group
Reporting group description: Participants received one dose of ChAd155-hIi-HBV high dose formulation vaccine at Day 1 in step B of the TH-HBV VV-001 (2017-001452-55) primary study and were evaluated for ChAd155-hIi-HBV shedding in the current ancillary study.	
Reporting group title	Control Group
Reporting group description: Participants received either one dose of HBc-HBs/AS01B-4 high dose formulation vaccine at Day 1 or one dose of negative control (placebo) at Day 1 in step B of the TH-HBV VV-001 (2017-001452-55) primary study and were evaluated for ChAd155-hIi-HBV shedding in the current ancillary study.	

Primary: Number of participants with Chimpanzee Adenovirus (ChAd)155 vector Deoxyribonucleic Acid (DNA) in throat swab above the limit of detection (LOD) of the quantitative polymerase chain reaction (qPCR) assay

End point title	Number of participants with Chimpanzee Adenovirus (ChAd)155 vector Deoxyribonucleic Acid (DNA) in throat swab above the limit of detection (LOD) of the quantitative polymerase chain reaction (qPCR) assay ^[1]
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End point description:

The biological samples of throat swab were collected at Days 1, 3, 8, 15 and Day 31 in the current ancillary study. The number of participants with ChAd155 vector DNA detected (i.e. above the LOD of the qPCR assay for ChAd155 vector) in throat swab is tabulated by group. The analysis was performed on the Exposed Set, which included all enrolled participants who received the study interventions at Day 1 in the TH HBV VV-001 (2017-001452-55) primary study and for whom data were available at the specified time points.

End point type	Primary
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End point timeframe:

At Days 1, 3, 8, 15, 31

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	B1 Group	Control Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	28		
Units: Participants				
Day 1 (N=23; 28)	0	0		
Day 3 (N=21; 25)	0	0		
Day 8 (N=23; 27)	0	0		
Day 15 (N=24; 27)	0	0		
Day 31 (N=22; 27)	0	0		

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with ChAd155 vector DNA in urine above the LOD of the qPCR assay

End point title	Number of participants with ChAd155 vector DNA in urine above the LOD of the qPCR assay ^[2]
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End point description:

The biological samples of urine were collected at Days 1, 3, 8, 15 and Day 31 in the current ancillary study. The number of participants with ChAd155 vector DNA detected (i.e. above the LOD of the qPCR assay for ChAd155 vector) in urine is tabulated by group. The analysis was performed on the Exposed Set, which included all enrolled participants who received the study interventions at Day 1 in the TH HBV VV-001 (2017-001452-55) primary study and for whom data were available at the specified time points.

End point type	Primary
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End point timeframe:

At Days 1, 3, 8, 15, 31

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: The analysis of the primary endpoint was descriptive i.e. no statistical hypothesis test was performed.

End point values	B1 Group	Control Group		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	28		
Units: Participants				
Day 1 (N=24; 28)	0	0		
Day 3 (N=23; 28)	0	0		
Day 8 (N=24; 28)	0	0		
Day 15 (N=24; 28)	0	0		
Day 31 (N=23; 28)	0	0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

Not applicable for this study. Safety was being investigated in the TH HBV VV-001 (2017-001452-55) primary study.

Adverse event reporting additional description:

There were no adverse events data collected during the current ancillary study. Safety results were evaluated in the TH HBV VV-001 (2017-001452-55) primary study and described in the respective results summary.

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	25.0
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Reporting groups

Reporting group title	Control Group
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Reporting group description:

Participants received either one dose of HBc-HBs/AS01B-4 high dose formulation vaccine at Day 1 or one dose of negative control (placebo) at Day 1 in step B of the TH-HBV VV-001 (2017-001452-55) primary study and were evaluated for ChAd155-hIi-HBV shedding in the current ancillary study.

Reporting group title	B1 Group
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Reporting group description:

Participants received one dose of ChAd155-hIi-HBV high dose formulation vaccine at Day 1 in step B of the TH-HBV VV-001 (2017-001452-55) primary study and were evaluated for ChAd155-hIi-HBV shedding in the current ancillary study.

Serious adverse events	Control Group	B1 Group	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 28 (0.00%)	0 / 24 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Control Group	B1 Group	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 28 (0.00%)	0 / 24 (0.00%)	

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: There were no adverse events data collected during this ancillary study. Safety results were evaluated in the primary study TH HBV VV-001 (2017-001452-55) and were described in the respective results summary.

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
03 June 2020	This protocol amendment 2 outlines measures that may be applicable during special circumstances (e.g., Coronavirus disease 2019 [COVID-19] pandemic). The purpose of the amendment is to protect patient's welfare and safety, and as far as possible ensure the potential benefit to the patient and promote data integrity. Additionally, since this study is ancillary to the TH HBV VV-001 (2017-001452-55) primary study, applicable changes have been incorporated from the TH HBV VV-001 protocol amendment 5.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported